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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/471,040  | 12/23/1999  | ULF TILSTAM          | SCH-1615-D1         | 6934             |
| 23599   | 7590        | 12/11/2007           | EXAMINER            |                  |
| MILLEN, WHITE, ZELANO & BRANIGAN, P.C.<br>2200 CLARENDON BLVD.<br>SUITE 1400<br>ARLINGTON, VA 22201 |             |                      | PESELEV, ELLI       |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 1623  |             |                      |                     |                  |
| MAIL DATE   |             | DELIVERY MODE        |                     |                  |
| 12/11/2007  |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|------------------------------|------------------------|---------------------|
|                              | 09/471,040             | TILSTAM ET AL.      |
| <b>Examiner</b>              | <b>Art Unit</b>        |                     |
|                              | Elli Peselev           | 1623                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 31 October 2007.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 4-15 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 4-15 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. \_\_\_\_\_.  
3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5)  Notice of Informal Patent Application  
6)  Other: \_\_\_\_\_.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2007 has been entered.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blumbergs et al (U.S. Patent No. 5,110,919) in view of Butler et al (U.S. Patent No. 5,506,352).

Blumbergs et al disclose crystalline fludarabine-phosphate but do not disclose said compound with a purity of at least 99.5%. However, since Butler et al disclose purification of a closely analogous arabinosyl-arabine-phosphate (column 5, lines 44-67 and column 6, lines 1-18), a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to purify the compound disclosed by Blumbergs et al in accordance with the method disclosed by Butler et al because such a person would have expected to produce a compound having the desired degree of purity.

Applicant's arguments filed October 31, 2007 have been fully considered but they are not persuasive.

Applicant contends that Blumbergs teaches that the recrystallization resulted in "no real improvement in purity". Applicant further contends that since Blumbergs suggests avoiding further recrystallization, the teaching by Blumbergs cannot be combined with anything, including Butler, to motivate a skilled worker to recrystallize fludarabine phosphate in an effort to improve its purity. This argument has not been found persuasive. The present claims are not directed to a process of preparing the claimed compound but to a product per se. It is generally acknowledged that it is desirable for the active component in a pharmaceutical composition to be as pure as possible. The specification on page 4, last paragraph discloses that according to the

prior art, the active ingredient previously could be obtained only at a purity of about 98.0-98.5%. The present claims are directed to a compound having a purity of 99.5% to greater than 99.85%. Absent unexpected results to obtaining the subject compound at purity of at least of 99>5% over the product having purity of about 98.5%, the claimed product is *prima facie* over the product known in the prior art and as taught by Blumbergs et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Elli Peselev*  
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